510K SUMMARY OF SAFETY AND EFFECTIVENESS FOR ESCORT M8 VITAL SIGNS PATIENT MONITOR MODEL 3810

1. Submitter Information:

Invivo Corporation
12601 Research Parkway
Orlando, Fl 32826

OCT 12 2006

Contact Person: Rusty Kelly
Title: Quality Control Manager
Telephone No.: (407) 275-3220 Ext: 166
Fax No.: (407) 206-9568
Date Prepared: July 5, 2006

2. Device Name:

Classification Name: Monitor, cardiac (incl. Cardiotachometer and rate alarm)

Propietary Name: Escort M8 Vital Signs Patient Monitor Model 3810

Product Codes:

Device	Product Code	CFR Reference	Class
ECG	DRT	870.2300	II
non invasive blood pressure	DXN	870.1130	II
invasive blood pressure	DSK	870.1110	II
temperature	FLL	880.2910	II
respiration	BZQ	868.2375	II
SPO_2 (Oximeter)	DQA	870.2700	II
$ETCO_2$ (Capnometer)	CCK	868.1400	II
arrhythmia detection	MHX	870.1025	II
transmitter and receiver	DRG	870.2910	II
recorder	DSF	870.2810	II
display	DXJ	870.2450	II

3. Device Description:

The Escort M8 Vital Signs Patient Monitor Model 3810 is a multiparameter patient monitor intended to monitor adult and pediatric patient vital signs for general hospital use. The Escort M8 contains the hardware and software needed to perform complex data gathering and signal processing tasks that allow it to produce accurate and reliable measurements of physiological parameters such as heart rate, ECG, non invasive blood pressure, temperature, respiration, SPO2, and capnometry (eTCO2 and FiCO2), provides arrhythmia detection and displays this information on an LCD display.

4. **Substantial Equivalence:**

The Escort M8 Vital Signs Patient Monitor is substantially equivalent to the following devices:

Zoe Medical Nightingale Monitoring System	510(k) K001775
Escort II + 400 Series (Escort Prism)	510(k) K014294
Polaris 2004 Capnograph	510(k) K040011
Masimo SET Radical Pulse Oximeter	510(k) K992340
Datascope Passport 2 with View 12 ECG Analysis Module	510(k) K020550

5. **Indications for Use**

The Escort M8 Vital Signs Patient Monitor is intended for use as a vital signs monitor for adult and pediatric patients in hospital settings.

6. **Comparison to Predicate Devices**

The Escort M8 Vital Signs Patient Monitor is a modification of the Zoe Medical Nightingale Monitoring System. This modification adds a capnometer, invasive blood pressure monitor, arrhythmia detector and alarm, strip chart recorder, replaces the existing oximeter, adds lead selectivity to ECG and increases the size of the display.

7. **Technological Characteristics**

A comparison of the technological characteristics of the Escort M8 Vital Signs Patient Monitor and the predicate devices has been performed. The results of this comparison demonstrate that the Escort M8 Vital Signs Patient Monitor is equivalent to the marketed predicate devices in technological characteristics.

8. **Environmental and non-clinical testing**

Applicable environmental and non-clinical testing was performed per UL60601 and IEC 60601-1-2 as well as other applicable standards and procedures. The Escort M8 Vital Signs Patient Monitor passed all tests.

9. **Performance data**

The performance data included in this submission to compare equivalency of the Escort M8 Vital Signs Patient Monitor with its predicate devices met the performance requirements for accuracy and precision and indicates substantial equivalence to the predicate devices. Equivalent performance in meeting user requirements was also determined.

10. Summary of performance Testing

Validation and Verification Testing confirmed that this device operates as designed and intended. The specifications for this device were verified in bench testing under simulated use conditions. Compliance to performance standards was confirmed by bench testing.

This device was validated using patient simulators under simulated use conditions. The functional requirements and user needs of the Escort M8 Vital Signs Patient Monitor were verified to have been met.

General

Parameter	Requirement	Pass/Fail
Electrical Safety	UL 60601-1:2003, IEC 60601-1-1:2000	Pass
EMC	IEC 60601-1-2	Pass
Biocompatibility	ISO 10993-1	Pass
Shock	IEC 60068-2-27	Pass
Vibration	IEC 60068-2-64	Pass

Invasive Pressure Monitoring

Parameter	Requirement	Pass/Fail
Measurement range	-10 to 300 mmHg	Pass
Measurement accuracy	± 2 mmHg or ± 2%	Pass
Heart Rate Range	30 to 240 bpm.	Pass
Heart Rate Accuracy	± 4 bpm	Pass
Sensitivity	5 uV/V/mmHg	Pass
Standard	IEC 60601-2-34: 2000	Pass

Capnometer

Parameter	Requirement	Pass/Fail
Accuracy 0 to 20 min	0 to 38 mmHg: ± 4 mmHg 39 to 99 mmHg: ± 12%	Pass
Accuracy 20 min and up	0 to 38 mmHg: ± 2 mmHg 39 to 99 mmHg: ± 5% of reading +0.08% for every 1mmHg above 38 mmHg	Pass
Measurement Range	0 to 99 mmHg ; 0 to 13.0 Vol%; 0 to 13.0 kPa	Pass
Flow Rate	50ml per min.	Pass
Respiration Rate	0 to 150 bpm	Pass
Respiration Accuracy	0 to 70 bpm : ± 1 bpm 71 to 120 bpm ± 2 bpm 121 to150 bpm ± 3 bpm	Pass
Standard	ISO 21647:2004	Pass

Transmitter and Receiver

Parameter	Requirement	Pass/Fail
Frequency	Spread spectrum 902 to 928 MHz	Pass
Transmission	Bidirectional with seamless auto-retry	Pass
FCC Licensing	47 CFR Part 15	Pass

Multiple Lead Selection on Cardiac Monitor

Parameter	Requirement	Pass/Fail
Leads	I, II or III selectable	Pass
5 Lead / Dual Vector	I, II, III, V, aVF, aVR, aVL.	Pass

The testing of AAMI/ANSI EC 13 will be completed prior to product release, testing still on-going.

Arrhythmia Detector and Alarm

Parameter	Requirement	Pass/Fail
Heart Rate Range	15 to 300 bpm.	Pass
Heart range accuracy	±2 bpm or ±1%, whichever is greater	Pass
Pacer rejection	Rejects all pulses of amplitude ±2mV to ±700mV and duration 0.1 to 2 ms with no tail	Pass
Tall T-Wave rejection	Without Arrhythmia Option: Rejects all T-Waves less than or equal to 120% of 1mV QRS. With Arrhythmia Option: Rejects T-Waves less than or equal to 60% of 1mv QRS.	Pass
Arrhythmia analysis	Asystole, Couplets, Bigeminy, Trigminy, Ventricular Tachycardia, Ventricular Fibrillation, Ventricular Rhythm, Ventricular runs, Multi-focal PVC's, and R-on-T.	Pass
Standard	AAMI/ANSI EC 57: 1998	Pass

Oximeter

Parameter	Requirement	Pass/Fail
Saturation Range	1% to 100%	Pass
Saturation Accuracy	70 to 100% ± 2 digits -no motion 70 to 100% ± 3 digits -motion 0 to 69% unspecified	Pass
Saturation Resolution	1%	Pass
Pulse rate range	25 to 240 Bpm	Pass
Pulse rate accuracy	25 to 240 ± 3 digits -no motion 25 to 240 ± 5 digits -motion	Pass
Pulse rate resolution	1 BPM	Pass

Display

Parameter	Requirement	Pass/Fail
Type	Color Active Matrix TFT LCD	Pass
Size	8.4 in./ 21.3 cm diagonal	Pass
Resolution	640 x 480 pixels	Pass
Number of Traces	4 channels	Pass

11. Quality System

This device is being designed and manufactured in a quality system that has been certified to EN 13485:2003 requirements, and conforms with the Medical Device Directive requirements found in the European Council Directive 93/42/EEC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2006

Invivo Corporation
c/o Mr. Rusty Kelly
Quality Control Manager
12601 Research Parkway
Orlando, FL 32826

Re: K062144
Trade Name: Escort M8 Vital signs Patient Monitor, Model 3810
Regulation Number: 21 CFR 870.1025
Regulation Name: Physiological Patient Monitor (With Arrhythmia Detection or Alarm)
Regulatory Class: Class II (two)
Product Code: MHX, CCK, DSK, DRT, DQA
Dated: July 26, 2006
Received: July 27, 2006

Dear Mr. Kelly:

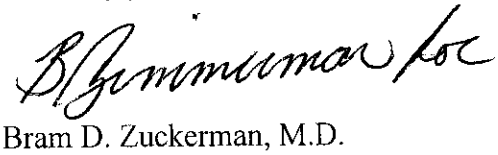
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240)276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510K Number: K062144

Device Name: **Escort M8 Vital Signs Patient Monitor Model 3810**

Indications for Use: The Escort M8 Vital Signs Patient Monitor Model 3810 is intended for use as a vital signs monitor for adult and pediatric patients in a hospital setting.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062144